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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/445,963 12/16/99 TANAKA

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HM12/0207
SUGHRUE MION ZINN MACPEAK & SEAS
2100 PENNSYLVANIA AVENUE NW
WASHINGTON DC 20037-3202

EXAMINER

DAVIS, N

ART UNIT

PAPER NUMBER

1642

DATE MAILED:

02/07/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.

09/445,963

Applicant(s)

TANAKA ET AL.

Examiner

Natalie A. Davis

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The use of ambiguous language makes it unclear whether the agent claimed is 5-aminolevulinic acid or a compound containing 5-aminolevulinic acid. It is also unclear if the agent is an ester, amide, salt hydrate or solvate.

Claims are not drawn to a method of use; thus the intended use of the agent will not be taken into consideration.

Claims 3 and 4 do not distinctly point out the difference between a diagnostically and pharmaceutically acceptable carrier.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1 and 3 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 1 and 3 are drawn to an agent or composition that is used for diagnosing malignant tumors. The specification discloses a composition comprising ¹³C-labeled 5-aminolevulinic acid that when administered accumulates at a

higher concentration in cancer cells than in muscle. Thus, malignant tumors can be detected by administering ^{13}C -labeled 5-aminolevulinic acid and examining the region where ^{13}C has accumulated through the measurement of ^{13}C -NMR. However, the specification does not teach the diagnosis of malignant tumors, only the detection of such tumors. It is not clear if the accumulation of ^{13}C -labeled 5-aminolevulinic acid is always indicative of the presence of tumor and whether it is predictive of the presence of a malignant tumor in a human. The specification does not make clear if the accumulation of ^{13}C -labeled 5-aminolevulinic acid is always indicative of only malignant tumors as opposed to a benign, pseudo-tumor or some other diseased state of the tissue.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Jichlinski, et al. Jichlinski, et al, discloses using an aqueous solution of delta-aminolevulinic acid to detect and treat bladder cancer.

7. Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by Kennedy et al. Patients with malignant tumors were given delta-aminolevulinic acid; afterwhich tumors were treated with photoactivating light to destroy the cancer.

8. Claims 3 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Kajiwara (JP 02111747). Kajiwara discloses ^{13}C -labeled 5-aminolevulinic acid and its derivatives for diagnostic purposes.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jichlinski, et al in view of Jaffe, et al. Jichlinski, et al discloses using delta-aminolevulinic acid to detect malignant tumors, but does not teach to use NMR as a method of detection. Jaffe, et al discloses using NMR to detect carbon -13 and nitrogen-15 isotopically replaced 5-aminolevulinic acid porphobilinogen complexes.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to detect malignant tumors using NMR since radioisotopes have been commonly used in the detection of malignant tumors.

Specification

11. This application filed under former 37 CFR 1.60 lacks the necessary reference to the prior application. A statement reading "This is a 371 of Application No. PCT/JP98/02648, filed 16 June, 1998," should be entered following the title of the invention or as the first sentence of the specification. Also, the current status of all nonprovisional parent applications referenced should be included.

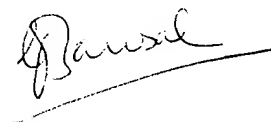
12. The disclosure is objected to because of the following informalities: The claims should begin with "we claim" instead of "claims". Appropriate correction is required.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie A. Davis whose telephone number is 703-308-6410. The examiner can normally be reached on M-F 8-4:30.

Art Unit: 1642

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4315 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Natalie A. Davis

January 26, 2001

GEETHA P. BANSAL
PRIMARY EXAMINER